Updates in Penile Cancer

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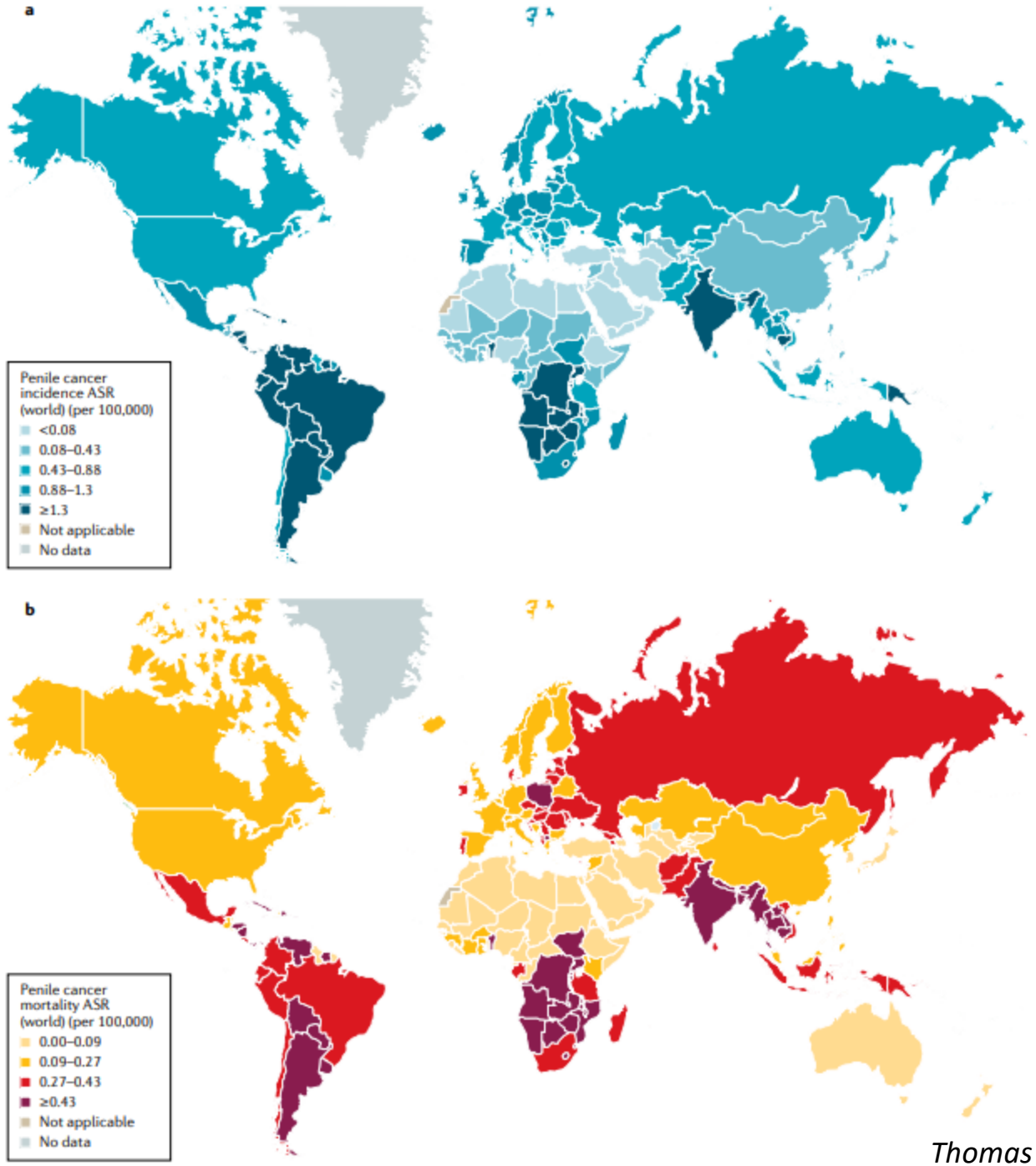
MaTOS Genitourinary
3/22/2025

Baylor St. Luke's Medical Center | DAN L DUNCAN COMPREHENSIVE CANCER CENTER | Baylor Medicine

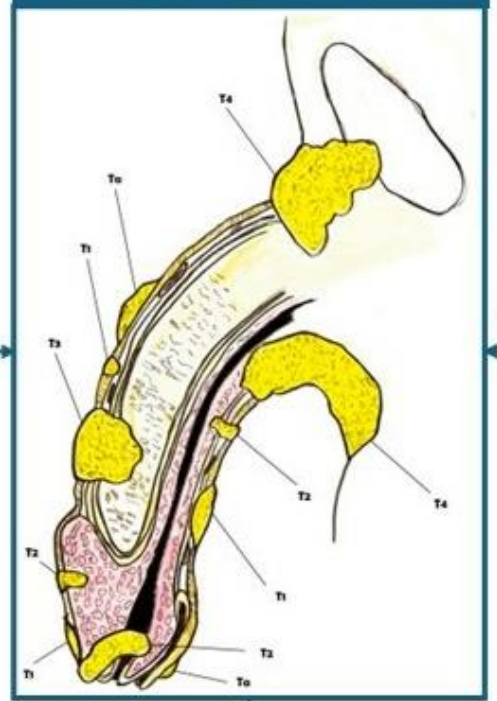


Thomas A,Necchi A et al. Nat Rev Dis Primers 2021

South America
Africa
South-Est Asia

Higher incidence Areas

Penile Cancer



Risk Factors

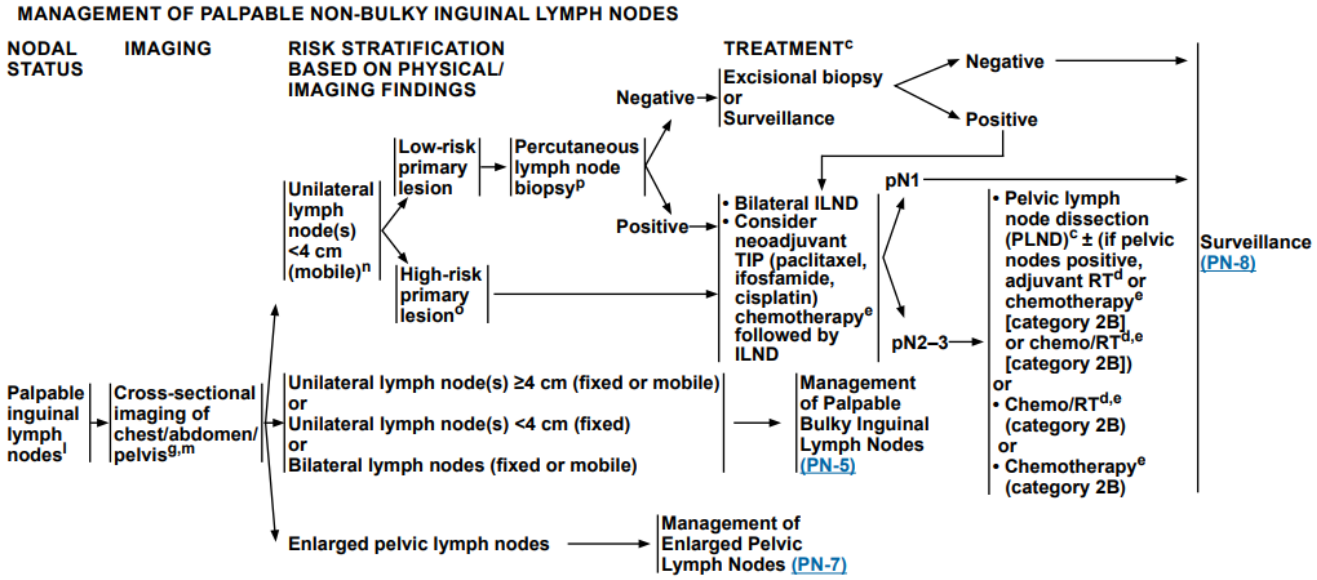
- HPV
- Smoking
- Hygiene
- Phimosis
- Obesity
- Sexual Behaviour
- Education
- Healthcare Access
- Chronic Inflammation
- Genes

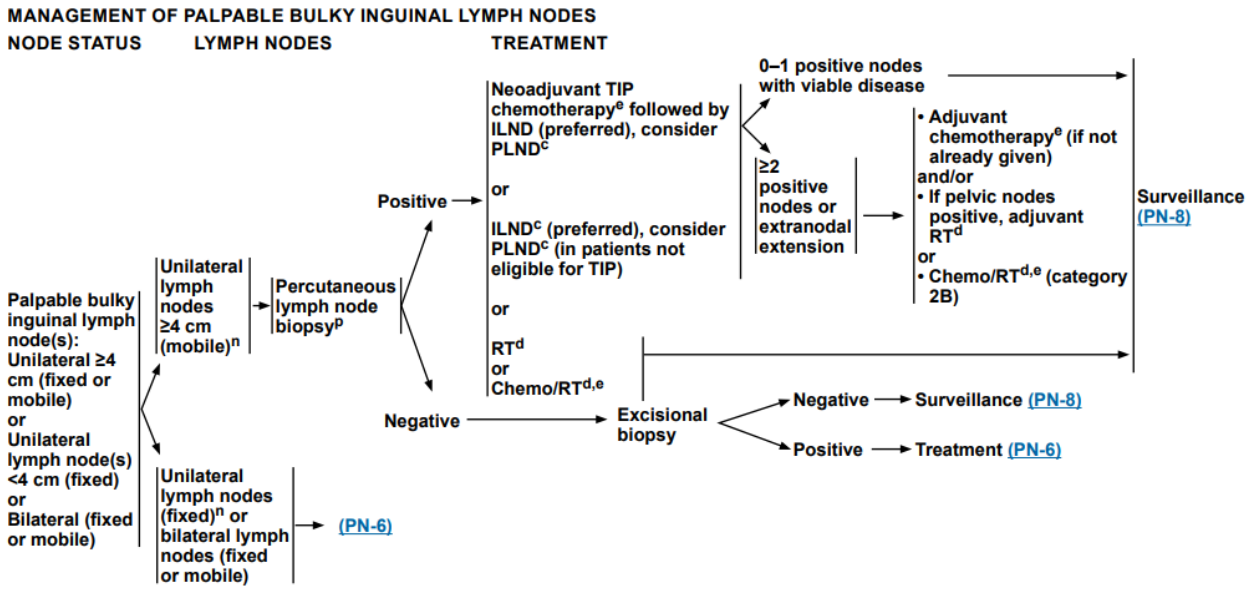
Patient Impact

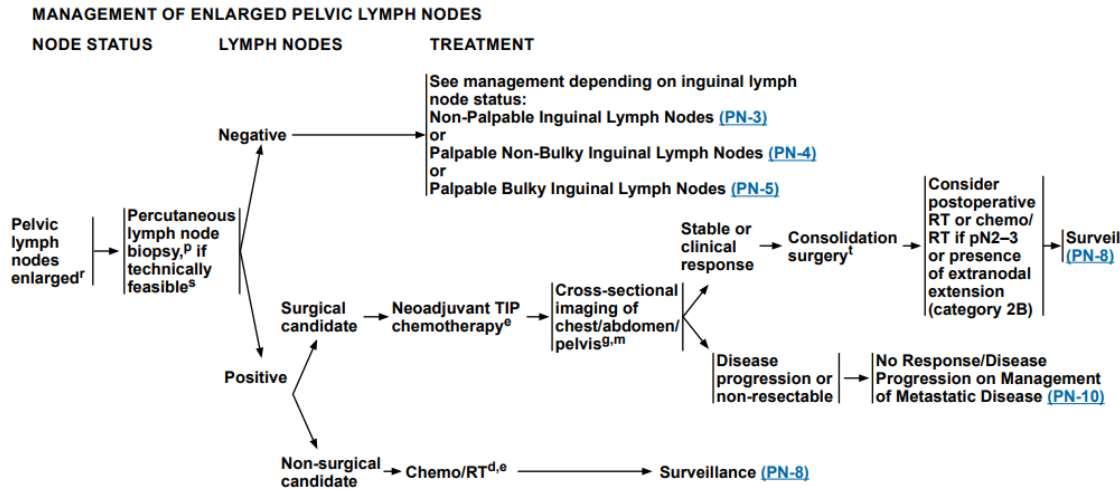
- Body image
- Masculinity
- Depression

Mutilating Surgery

Amicuzi U,et al. Diagnostics 2024







NCCN Guidelines Penile Cancer V 2.2005.

Neoadjuvant Chemotherapy Prior to ILND or PLND
Preferred Regimen • TIP (paclitaxel, ifosfamide, and cisplatin)

Adjuvant Chemotherapy Following ILND or PLND
Preferred Regimen • TIP
Other Recommended Regimen • 5-FU + cisplatin[3,4]

First-Line Systemic Therapy for Metastatic/Recurrent Disease
Preferred Regimen • TIP
Other Recommended Regimens • 5-FU + cisplatin • 5-FU + cisplatin + pembrolizumab followed by pembrolizumab maintenance therapy • 5-FU + carboplatin + pembrolizumab followed by pembrolizumab maintenance therapy

Subsequent-Line Systemic Therapy for Metastatic/Recurrent Disease
Preferred Regimen • Clinical trial • Pembrolizumab, if unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair-deficient (dMMR) tumor that has progressed following prior treatment and no satisfactory alternative treatment options,[6,7,8] or if tumor mutational burden-high (TMB-H), TMB ≥10 mut/Mb in patients who have progressed on previously approved lines of therapy[9]
Useful in Certain Circumstances • Paclitaxel • Cetuximab

NCCN Guidelines Penile Cancer V 2.2005.

EAU-ASCO Collaborative Guideline Update for Penile Cancer 2023

Recommendations	Strength Rating
When surgical staging is indicated, offer dynamic sentinel node biopsy (DSNB). If DSNB is not available and referral is not feasible, or if preferred by the patient after being well informed, offer inguinal lymph node dissection (ILND) (open or video-endoscopic)	Strong
Offer adjuvant radiotherapy (with or without chemo sensitization) to patients with pN2/N3 disease, including those who received prior neoadjuvant chemotherapy	Weak
Offer definitive radiotherapy (with or without chemo sensitization) to patients unwilling or unable to undergo surgery	Weak
Offer radiotherapy (with or without chemo sensitization) to cN3 patients who are not candidates for multi-agent chemotherapy	Weak
Offer patients with distant metastatic disease, platinum-based chemotherapy as the preferred approach to first-line palliative systemic therapy	Weak
Do not offer bleomycin because of the pulmonary toxicity risk	Strong
Offer patients with progressive disease under platinum chemotherapy the opportunity to enroll in clinical trials, including experimental therapies within phase I or basket trials	Strong
Offer radiotherapy for symptom control (palliation) in advanced disease	Strong

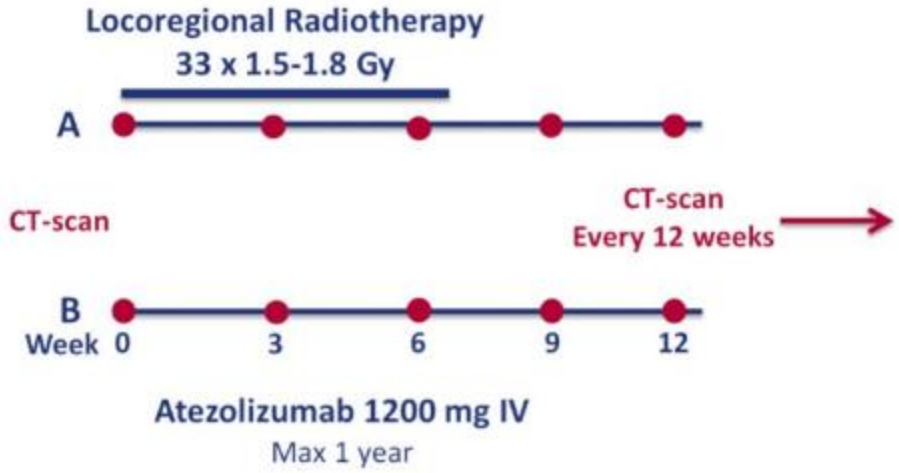
Brouwer O et al JCO Oncology Practice 2023

PERICLES: Phase II Trial Atezolizumab +/- XRT for Advanced Penile SCC

PERICLES: A single-centre phase 2 study with two treatment arms (non-randomized)

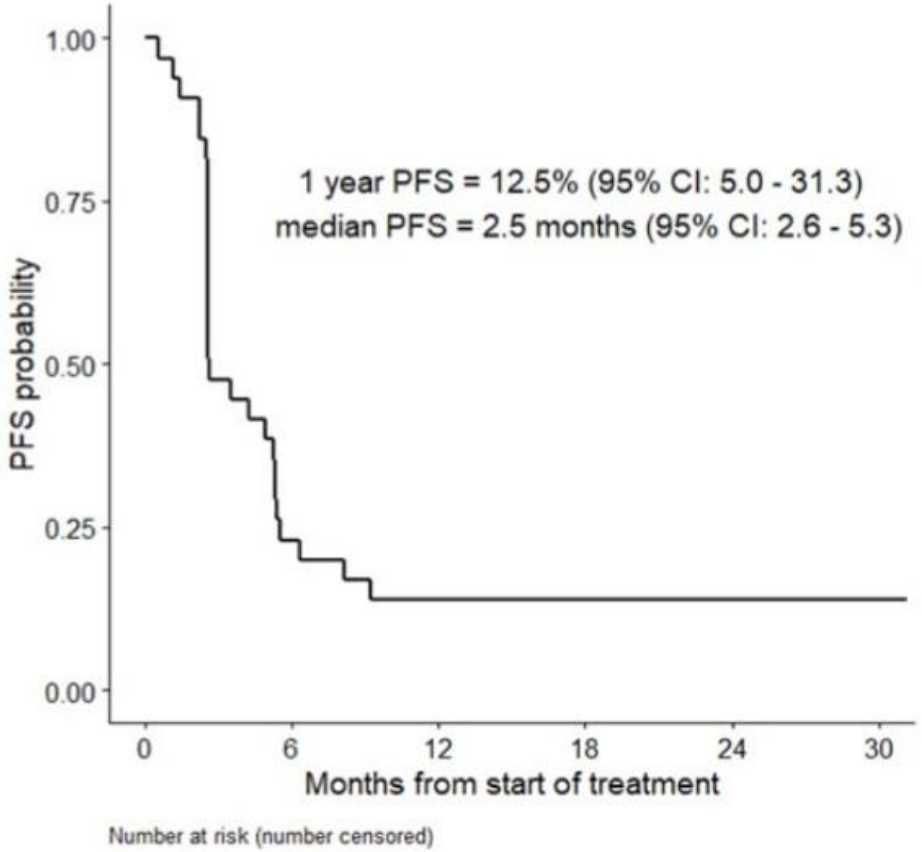
Advanced penile cancer N=32
Distant metastases OR LRAPC:
- inoperable primary tumor
- palpable nodes >3cm or fixed
- suspicion of extra-nodal extension
- pelvic node involvement

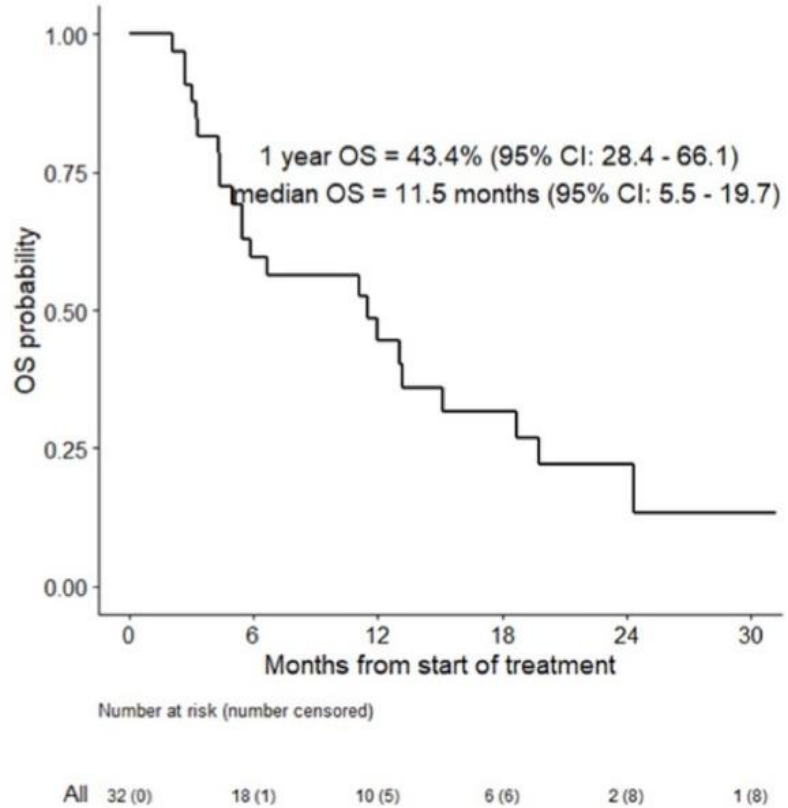
- WHO 0-1
- Previous treatment allowed except anti-PD-(L)1



Primary objective: 1-year progression free survival ≥ 35%, to exclude 15% (RECIST 1.1)
Secondary objectives: OS, response rate, toxicity (NCI-CTCAE V4)

De Vries HM,et al. J Clin Oncol. 2023

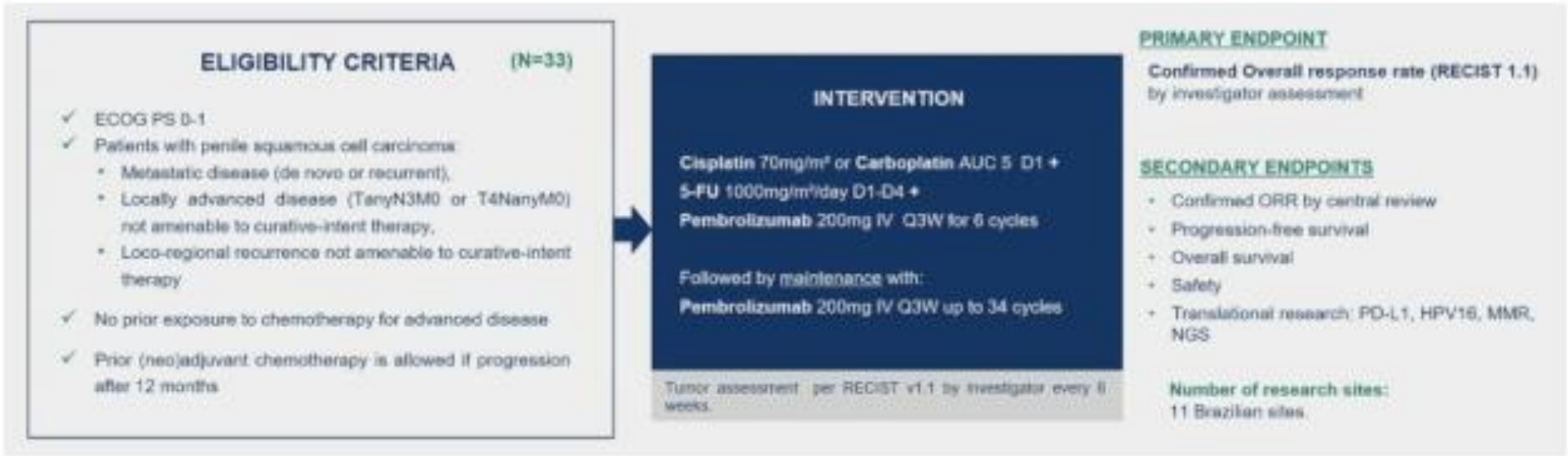




Best overall response in RECIST 1.1. evaluable patients			
	Arm A, n=18 (%): Atezo + RT	Arm B, n=12 (%): Atezo	Total, n=30 (%)
BOR	**8 (44)**	**2 (17)**	**10 (33)**
Complete response	2 (11)	1 (8.3)	3 (10)
Partial response	6 (33)	1 (8.3)	7 (23)
Stable disease	2 (11)	1 (8.3)	3 (10)

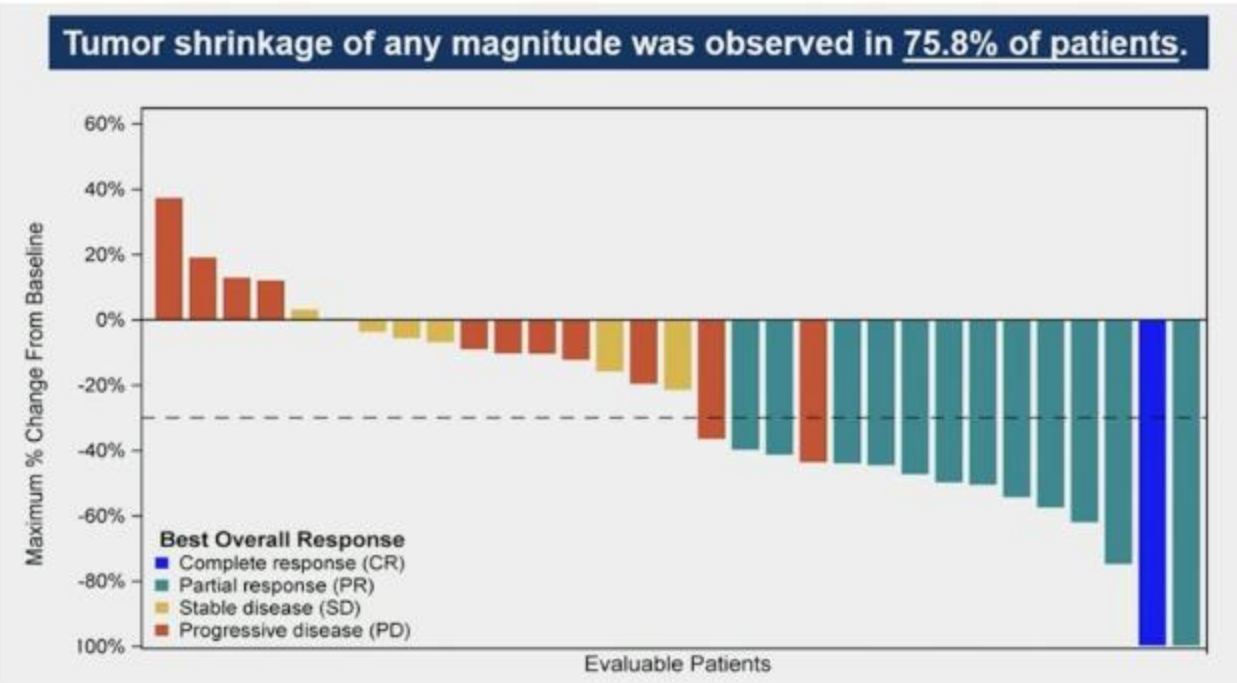
De Vries HM,et al. J Clin Oncol. 2023

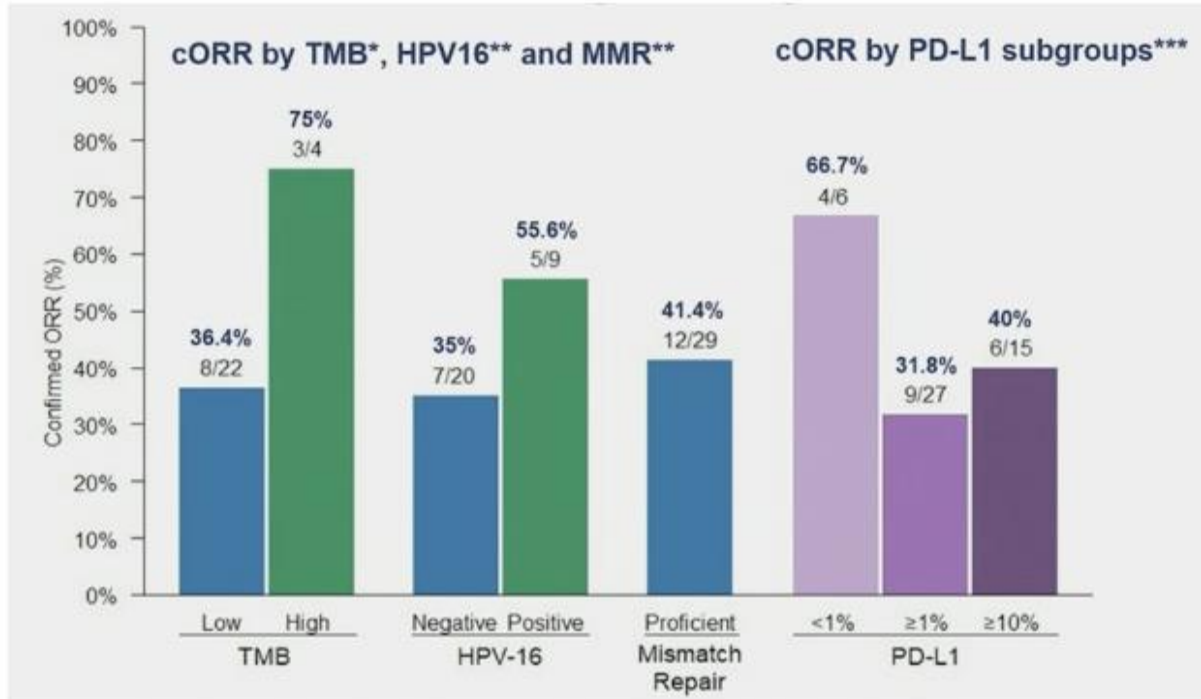
HERCULES: Phase II of Pembrolizumab plus Platinum Chemotherapy as 1st Line Systemic Therapy in Advanced Penile Cancer



Maluf FC, et al. ASCO Annual Meeting 2024, urotoday.com

Efficacy Outcome	N=33*
Confirmed ORR by investigator	13 (39.4%); (95% CI, 22.9 – 57.9)
Best overall response by investigator	
Complete Response	1 (3.0%)
Partial Response	12 (36.4%)
Stable Disease	7 (21.2%)
Progressive Disease	11 (33.3%)
Unevaluable**	2 (6.1%)
Confirmed ORR by central review	14 (42.4%); (95% CI, 25.5 – 60.8)
Clinical benefit rate by investigator (CR, PR, SD ≥ 24 weeks)	15 (45.5%); (95% CI, 28.1 – 63.7)





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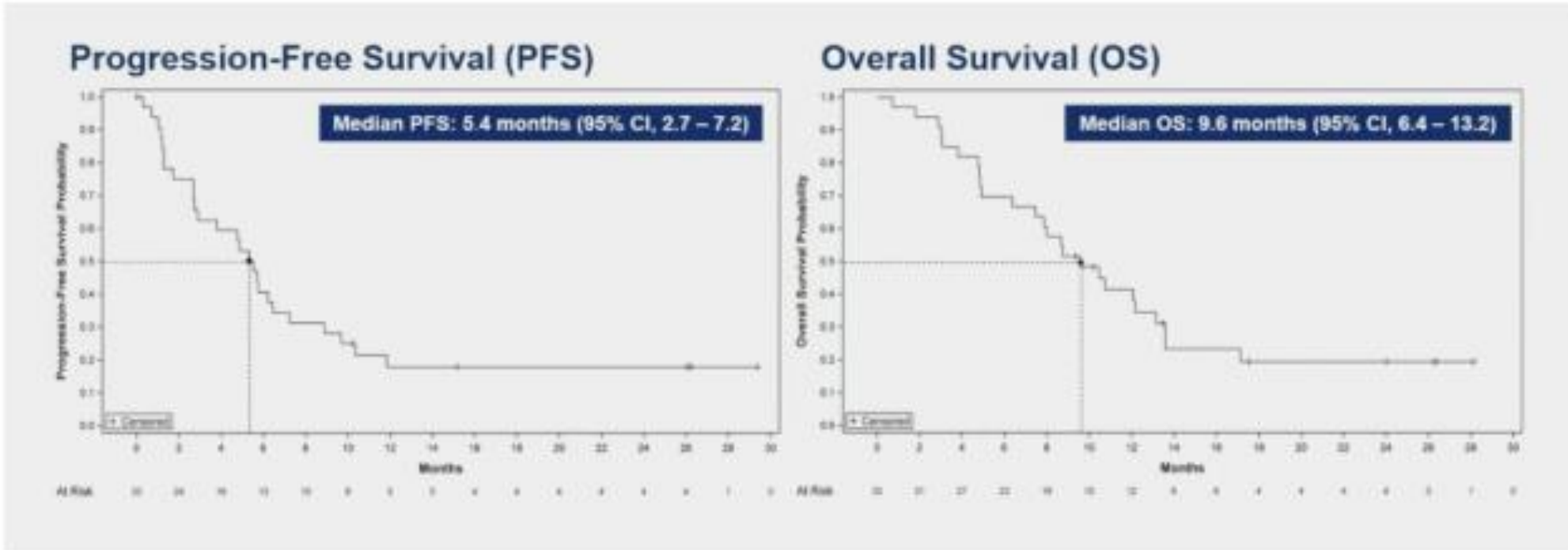
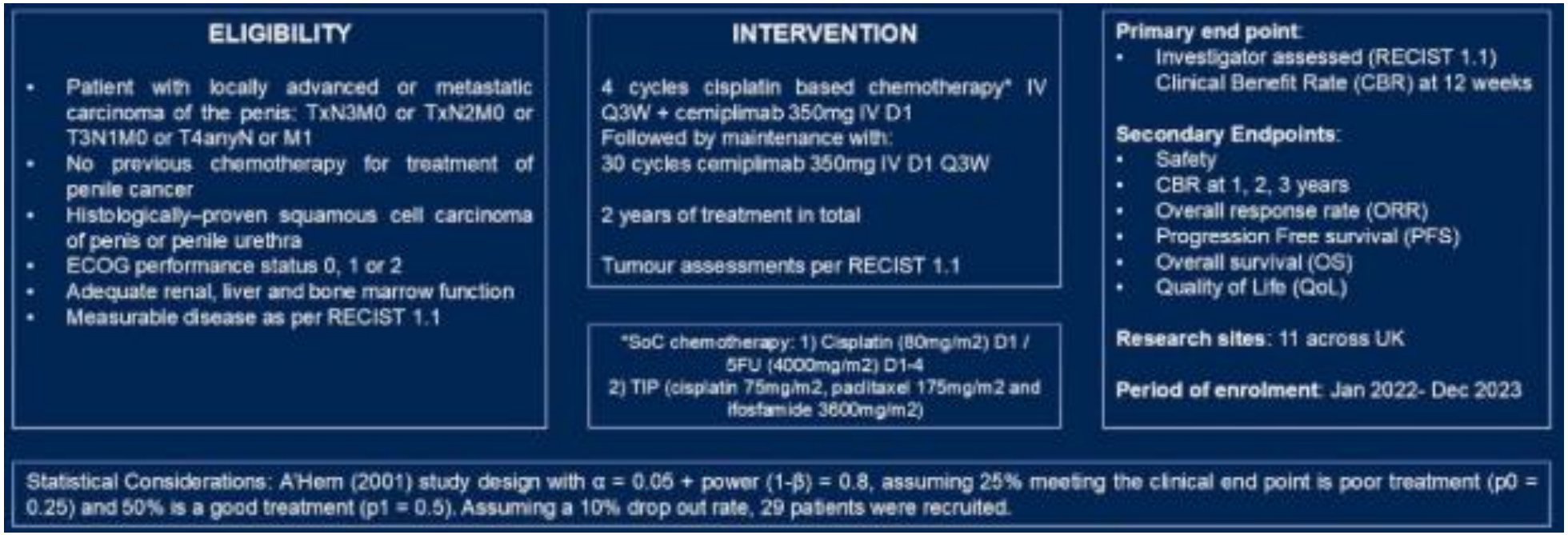


Maluf FC, et al. ASCO Annual Meeting 2024, urotoday.com

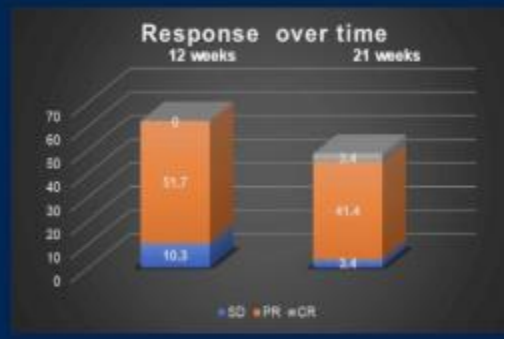
EPIC-A: Phase II Trial of Cemiplimab plus SOC Followed by Maintenance Cemiplimab in LA/Metastatic Penile Carcinoma



Bahl A, et al. 2025 ASCO Genitourinary Cancers Symposium, urotoday.com

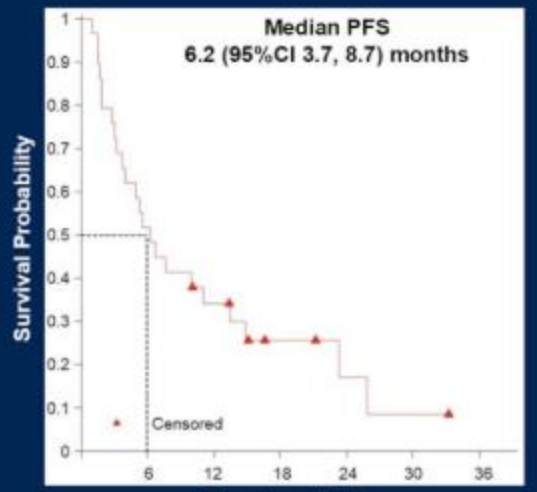
Efficacy: Clinical Benefit Rate (CBR)

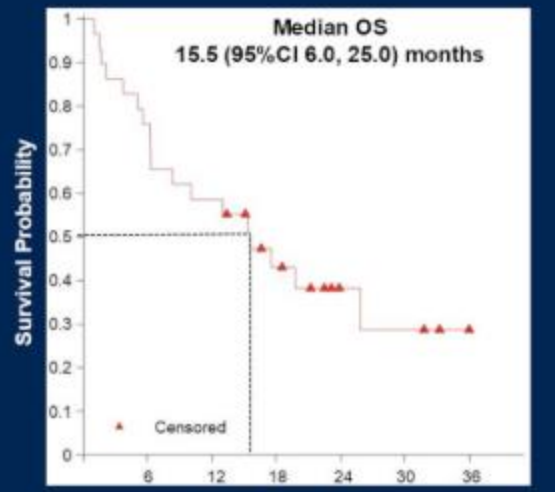
Efficacy outcome	N=29
12 weeks	
Clinical benefit rate (CBR)	62.1% (95%CI 44.4%, 79.7%)
CR	0
PR	15 (51.7%)
SD	3 (10.3%)
Objective response rate (ORR)	51.7% (95%CI 34.4%, 68.6%)
21 (12+9) weeks	
Clinical benefit rate (CBR)	48.3% (95%CI 31.4%, 65.6%)
CR	1 (3.4%)
PR	12 (41.4%)
SD	1 (3.4%)
Objective response rate (ORR)	44.8% (95%CI 28.4%, 62.4%)



95%CI lower limit for both ORR and CBR is higher than the null hypothesis limit of 25%

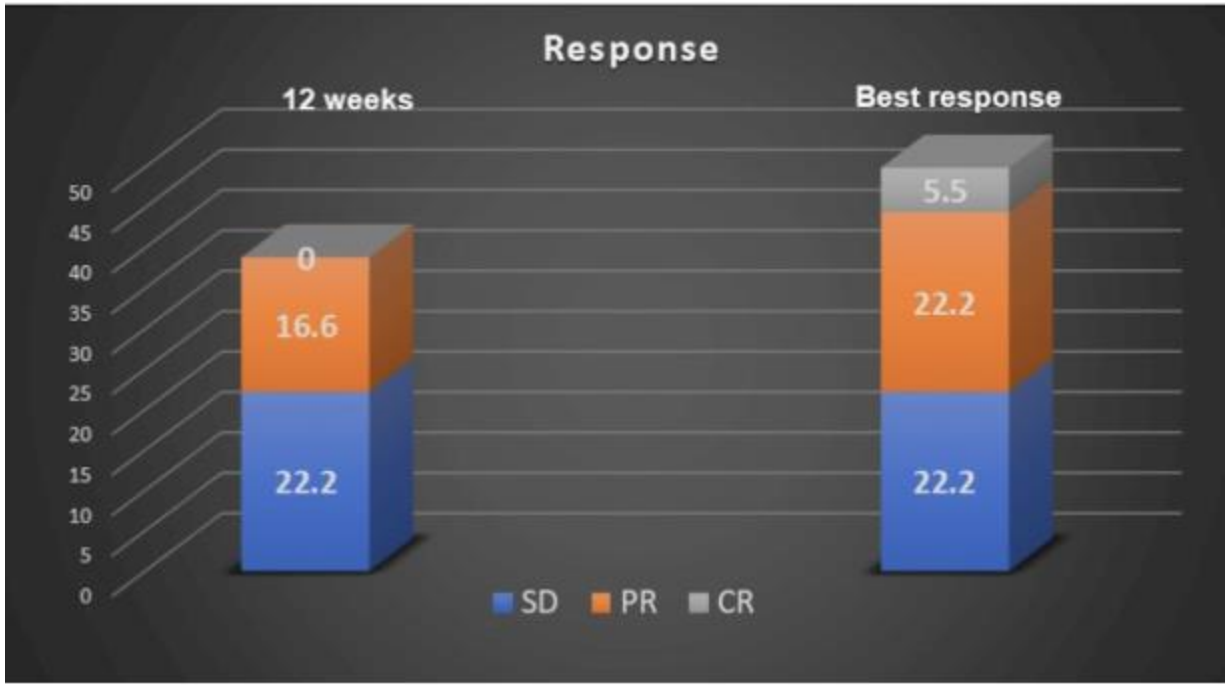
Survival outcomes: PFS and OS

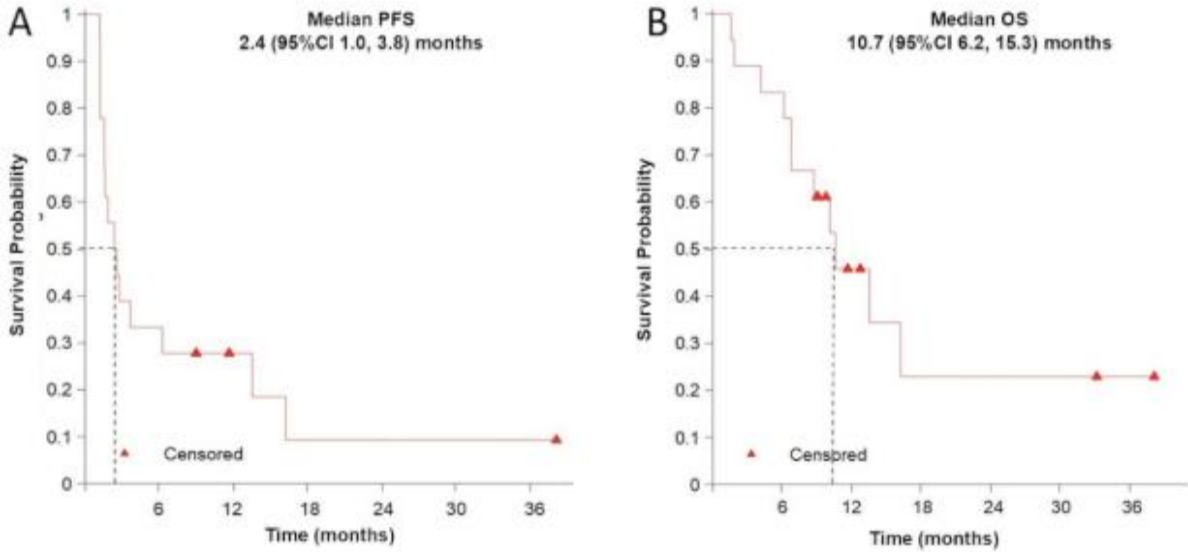




Bahl A, et al. 2025 ASCO Genitourinary Cancers Symposium, urotoday.com

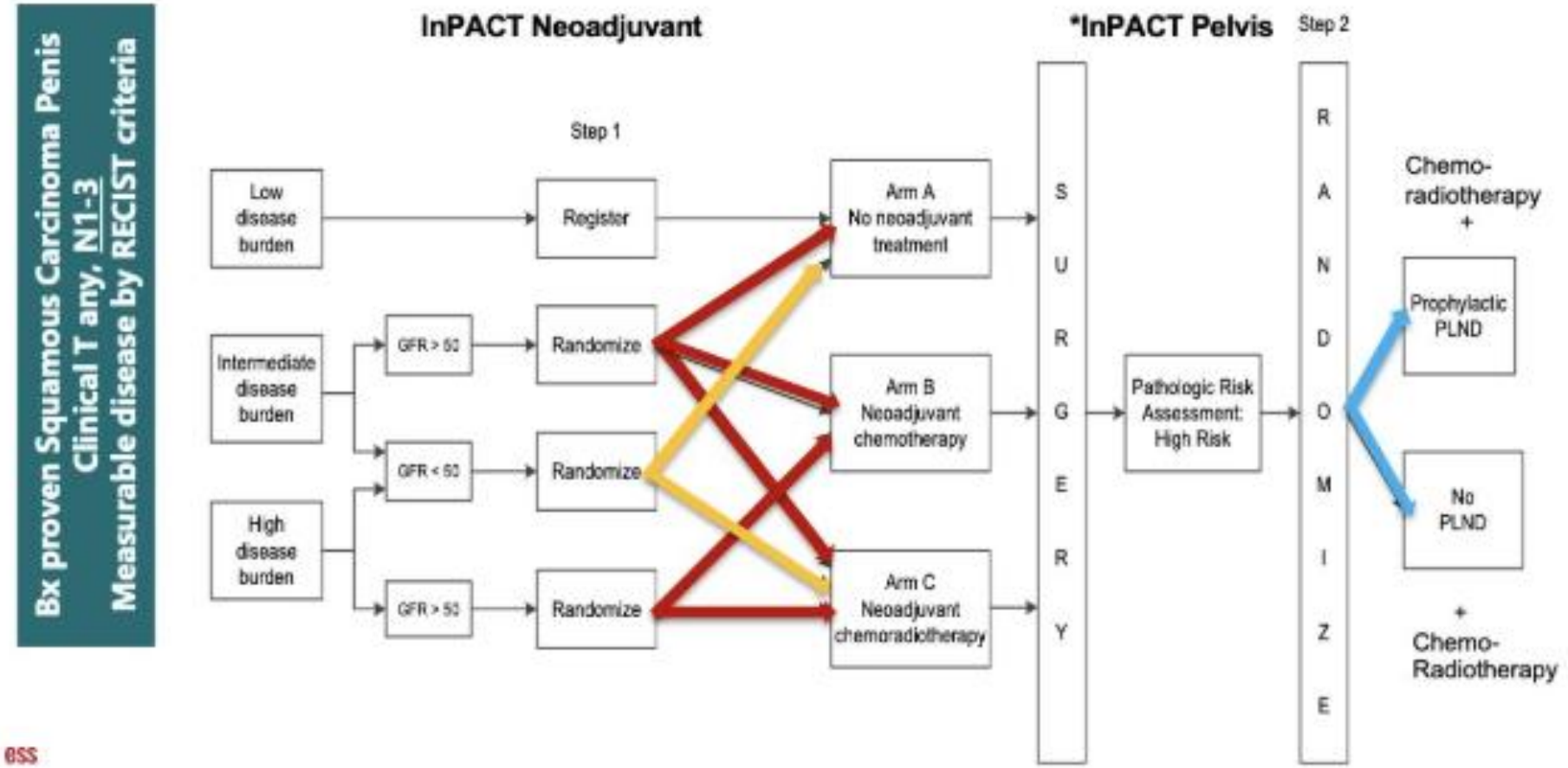
EPIC-B: Phase II Trial of Cemiplimab as First-Line Treatment in Advanced Penile Carcinoma





Bahl A, et al. 2025 ASCO Genitourinary Cancers Symposium, urotoday.com

InPACT (ECOG-EA8314): Phase 3 of ILD Alone or After Chemotherapy with or Without XRT for Patients with Advanced Penile Cancer



Thank You


Baylor St. Luke's Medical Center
Dan L Duncan
Comprehensive Cancer Center
O'Quinn
Medical
Tower